

REMARKS

Claims 1-6 are pending in the instant application. Claim 1 has been amended; support for the amendments are on page 3, lines 30-34 of the specification.

Rejection under 35 USC 102(b):

The Examiner has rejected claims 1-3 as being anticipated by Maitra (US 5,874,111). Applicants respectfully traverse. The Maitra reference fails to teach the limitations as recited in claims 1-3. The Examiner alleges that Maitra discloses water-soluble drugs coated with poloxamer, citing Figure 1 and claim 7. Figure 1 shows the in-vivo activity of particles that are less than or equal to 250nm in size. Additionally, Maitra states “[P]articles smaller than 7µm and specifically particles are not filtered in the lung (*emphasis added*) and their biodistribution is dependent on their interaction with reticuloendothelial system (RES)”, which clearly indicates that the reference teaches away from the instant claims. In the instant case, the pharmaceutical dosage form is for use in dry powder inhalation, clearly intended for administration to the lungs, thus the Maitra reference does not teach the limitations of the instant claims. Further, no where in Maitra is it taught or nearly suggested to prepare pharmaceutical dosage forms having an average mass median aerodynamic diameter (MMAD) of 0.5-15µm. In view of the foregoing arguments, it is clear that Maitra does not teach the instantly claimed invention and withdrawal of the rejection is respectfully requested.

Rejection under 35 USC 102(e):

The Examiner has rejected claims 1-6 as being anticipated by Weers et al (US 6,309,623). Applicants respectfully traverse. The Weers reference fails to teach the invention as recited in claims 1-6. Weers claims and discloses respiratory dispersion of bioactive ingredients having a MMAD of less than 5µm with the use of perforated microstructures. See col. 4, lines 30-34. The reference tangentially states that surfactants such as poloxamer may be optionally associated with the perforated microstructures. See col. 16, lines 9-11. The instant invention on the other hand does not have any perforated microstructures. It is drawn to the bioactive drug being coated with of a fatty acid, an alcohol derivative or a poloxamer. The cromolyn sodium included and discussed in the examples III and IV cited in Weers constitute the perforated microstructure to which poloxamer may be optionally associated. By contrast, the instant claims do not have a perforated microstructure within which the bioactive molecule is placed. Thus, the Weers reference does not teach or fairly suggest the instantly claimed invention and withdrawal of the rejection is respectfully solicited.

Rejection under 35 USC 103(a):

The Examiner has rejected claims 1-6 as being unpatentable over Weers or Baichwal (US 5,738,865). Applicants respectfully traverse.

The Examiner has indicated that the only difference between the teachings of Weers and the instant claims is that Weers does not have any examples drawn to the use of sorbitan esters. This is incorrect. Weers does not provide any guidance for the use of a fatty acid, an alcohol derivative or a poloxamer as a coating material for a solid active ingredient in a pharmaceutical dosage form, rather it teaches the use of poloxamer as a surfactant that may be associated with a perforated microstructure that holds the bioactive moiety. Weers does not teach the instantly claimed invention as discussed in the 35 USC 102(e) section; the differences between the Weers reference and the instant claims are numerous and one of ordinary skill in the art would not have been motivated to prepare a pharmaceutical dosage form as instantly claimed from the teachings of Weers.

MPEP § 2143.01 specifies that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine reference teachings. Instantly, the Baichwal reference does not provide any suggestion or motivation to modify the use of poloxamer or sorbitan esters as coating materials for any use, let alone affecting the rate releasing activity of the bioactive molecule. The Examiner has not provided any indication as to the suggestion or motivation necessary or an expectation of success that may be provided by the teachings of Baichwal. Additionally, the reference makes no indication, suggestion or teaching that would enable one of ordinary skill in the art to affect the MMAD of the end pharmaceutical dosage form by employing the coating material as instantly claimed. For these reasons, the Baichwal reference does not teach or fairly suggest the instant claims and withdrawal of the rejection is respectfully requested.

In view of the above amendments and remarks, Applicants respectfully submit that this application is now in condition for allowance and earnestly request such action.

If any points remain at issue which can best be resolved by way of a telephonic or personal interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

AMENDMENT
U.S. Appln. No. 10/085,972

Respectfully submitted,



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